

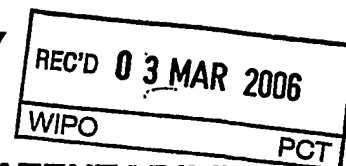
PATENT COOPERATION TREATY



PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference 4556PTWO-ca		FOR FURTHER ACTION See Form PCT/PEA/416	
International application No. PCT/EP2004/052709		International filing date (day/month/year) 28.10.2004	Priority date (day/month/year) 29.10.2003
International Patent Classification (IPC) or national classification and IPC C12P19/02, A23C9/123, A23C9/12			
Applicant INALCO S.P.A. et al.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of 3 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 10.08.2005		Date of completion of this report 21.02.2006	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer Graham, J Telephone No. +49 89 2399-7368 	

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2004/052709

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-8 as originally filed

Claims, Numbers

1-19 received on 08.08.2005 with letter of 08.08.2005

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☒ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☒ the claims, Nos. 20
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-19
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-19
Industrial applicability (IA)	Yes: Claims	1-19
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

**INTERNATIONAL PRELIMINARY
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Re Item I

Basis of the report

Basis for the amended independent claims 1 and 19, dated 8th August 2005, can be found at lines 18 to 31 on page 4 of the application as originally filed. The requirements of Art. 34(2)(b) PCT are therefore met.

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

Reference is made to the following documents:

- D1: EP-A-0 122 104 (ROBERTS, JAMES GORDON) 17 October 1984 (1984-10-17)
- D2: FR-A-2 581 998 (JAY FRANCOIS) 21 November 1986 (1986-11-21)
- D3: US-A-3 981 773 (GALZY ET AL) 21 September 1976 (1976-09-21)
- D4: US-A-6 057 135 (IBRAHIM ET AL) 2 May 2000 (2000-05-02)
- D5: US-A-4 467 034 (VOELSKOW ET AL) 21 August 1984 (1984-08-21)
- D6: EP-A-0 232 556 (BORCULO COOEP WEIPROD; STICHTING NL I
ZUIVELONDERZOEK; BORCULO COOEP W) 19 August 1987 (1987-08-19)

D1 discloses multi-cultured milk based products. D2 discloses the addition of yeast to lactoserum in order to obtain a composition comprising galactose and yeast via lactose fermentation. D3 discloses the fermentation of lactoserum to produce galactose. D1 to D3 neither disclose the maintenance of a **constant** pH value of 7.5 or less during fermentation, nor the period of time at said constant pH being between 16 to 24 hours and the addition of a base in order to maintain the said pH value. Moreover, the micro-organisms in D3 are mutated and selected by human intervention.

D4 discloses a process of manufacturing D-tagatose from whey via the intermediary product of galactose. Although D4 mentions the addition of ammonium hydroxide at the fermentation stage to maintain the pH between 4.5 and 5.5 it is silent concerning the time. Moreover, the whey is ultrafiltered to obtain a lactose permeate with a lower protein content than whey and consequently, the whey is considered to have been subjected to a purification treatment. D5 discloses a method of producing lactic acid via fermentation but

is silent with respect to galactose. D6 discloses the fermentation of whey (e.x. II) to produce and isolate lactic acid whereby a significant amount of galactose is also produced (table A).

The subject-matter of independent claims 1 and 19 and dependent claims 2 to 18 is therefore novel (Article 33(2) PCT).

D3, which is considered as the closest prior art, teaches the method of fermenting lactoserum with Lactobacteriaceae (col. 2, lines 43 - 44) in order to produce galactose. Taking into consideration that the micro-organism's technical characteristics are relevant as opposed to their history (i.e. wild strain or mutant), D3 essentially differs from the subject matter claimed in that the fermentation parameters are unspecified.

The problem to be solved by the subject matter claimed is therefore regarded as the provision of an alternative process of producing galactose from milk or milk serum.

D6 teaches the fermentation of a medium comprising whey and skimmed milk (e.x. II) at a constant pH of 6 to produce and isolate lactic acid. Table A teaches that fermenting for 16 hours produces 27.6 grams of galactose per litre and fermenting for 24 hours produces 11.6 grams of galactose.

The skilled man in the art knowing from D6 that a significant amount of galactose is produced at a constant pH of 6 for 16 to 24 hours would combine the teachings of D6 with D3 and arrive at the subject matter claimed. The solution to the problem posed is therefore not considered to involve an inventive step (Article 33(3) PCT).

Dependent claims 2 to 18 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step.

Re Item VIII

Certain observations on the international application

The wording "ranges" in claim 9 causes a lack of clarity (Art. 6 PCT) as it contradicts the term "constant". The claim has been interpreted that the constant pH is between 5.0 and

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7.5 and not that it "changes" between 5.0 and 7.5.